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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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PATENT DEPARTMENT
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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,230	WAN ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-43* is/are pending in the application.

4a) Of the above claim(s) *24-32 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the response filed 11/17/06, no claim has been added, amended or cancelled.

Applicants have continued to traverse the restriction between Groups I (claims 24-32, 42-43) and II (claims 33-41). Applicants have argued that they can see no distinction between them. The examiner will concede that it could be argued that the invention of claim 24 could be viewed as encompassing the invention of claim 33, and that a restriction (as opposed to election of a subgenus) might not be fully justified. But even if true, the point is largely moot, since there would have been nothing improper about requiring election of one of two subgenera, namely: (i) a process in which cysteine sulfhydryls are blocked or (ii) a process in which cysteine sulfhydryls are not blocked. Implicitly this has been done, in fact as applicants have elected a process in which sodium sulfite/sodium tetrathionate is the agent that is used to block cysteine residues. Thus, even if the restriction (*per se*) were to be withdrawn at this particular point, the election of a subgenus would still be in force. That is, applicants have elected a process in which blocking of cysteine sulfhydryls is a requirement; claim 24, by contrast, does not require or suggest blocking of cysteine sulfhydryl groups. Consider the following hypothetical claims:

100. A method comprising the step of walking into a laboratory.

101. The method of claim 100 further comprising synthesizing any one of 10^{99} steroids.

102. The method of claim 100 further comprising synthesizing any one of 10^{99} peptides.

103. The method of claim 100 further comprising synthesizing any one of 10^{99} cephalosporins.

104. The method of claim 100 further comprising testing a series of blood samples for the presence of any one of 100 different compounds using any one of 10,000 different assay methods.

105. The method of claim 100 further comprising treating any one of 20 different diseases in a rat using any one of 10^{99} different compounds.

Suppose that an examiner required election of a specific method, and in response the applicant elected a method of synthesizing any one of 50 billion enkephalin analogs. It is the examiner's position that in such a scenario, the examiner would be fully justified in withdrawing each of claims 101 and 103-105 from consideration, at least in the event that he (or she) could come up with a valid §103 rejection of claim 102. As for claim 100, a decision by the examiner to abstain from withdrawing this claim would be of no benefit to the applicant, since any valid §103 rejection which is applied against claim 102 could also be applied against claim 100. Thus, while some might argue that the decision by the examiner to abstain from withdrawing claim 100 is worthy of criticism, the question is, for all practical purposes, entirely moot with respect to the final outcome. Continuing with this hypothetical example, suppose that the applicant and examiner could reach an agreement as to which of the 50 billion enkephalin analogs are both novel and enabled. In such a scenario, the examiner would, in general, be obligated to rejoin claim 100 but with all of the limitations agreed upon in claim 102. However, such a claim would be identical in scope

to the claim (amended claim 102) which the examiner and applicant had agreed were allowable.

Consider again the claims of the instant application. Suppose that an agreement were reached that, in the event claim 33 were limited to a method of blocking cysteine residues of the protein identified as SEQ ID NO: 1, that the claim (claim 33) would become allowable. Under such a scenario, it would become appropriate for this examiner to rejoin claim 24, provided that all limitations of claim 33 were incorporated therein, and provided also that the protein were limited to SEQ ID NO: 1. The point is that the fact that claim 24 is withdrawn at the present time does not mean that the examiner is necessarily free of the obligation to rejoin claim 24 at a later time (provided that it contains the limitations agreed to in the elected group).

The issue of restriction, however, is now superceded by the issue of obviousness. If claim 24 were to be rejoined at the present time, it would be rejected over the same grounds that are applied in this Office action. If the §103 rejections set forth below (and previously) prove to be justified (as the examiner argues that they are), then claim 24 will not be allowable anyway; as such, the question of whether claim 24 should have been rejoined is moot, at least at the present time. If, on the other hand, it turns out that claims 33-38 prove to be novel in their present form, then it may become appropriate to rejoin claim 24, provided of course that the limitations of claim 33 are incorporated therein. The restriction is

maintained at the present time.

Claims 24-32 and 39-43 remain withdrawn from consideration.

Claims 33-38 are examined in this Office action.

The abbreviation "D.E." is used hereinbelow to denote diatomaceous earth.

✦

Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of USP 6,995,246. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.

✦

Claim 33 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending application Serial No. 10/873801. Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

✦

Claims 33-38 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent on a non-elected claim. In addition, the objective of merely "removing particles" is not consistent with the required process step, i.e., sulfitolysis of sulfhydryl groups. Some other, more suitable objective of the claimed method should be stated. As a first step, it is suggested that claim 33 be cast in independent form.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 33, 34, 38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

As indicated previously, Hsu discloses a method for obtaining KGF from lysed bacteria which expressed the KGF. Cell lysis is also disclosed (e.g., col 11, line 10+). Hsu also discloses (col 12, line 25+) removal of endotoxins. Also disclosed (col 11, line 19) is the use of a "filter aid" to clarify the cell lysate. Also disclosed (e.g., col 2, line 56+) is blocking of cysteine sulfhydryl groups. Hennan discloses (col 10, line 41) that D.E. is useful for preventing clogging of filters when filtering protein solutions that contain precipitates. Hennan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins. Colpan discloses a method for removal of cellular debris comprising a filtration step. A preferred filtration aid (col 2, line 31+) is D.E. Colpan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins. Thus, a practioner of the Hsu invention would purify KGF from lysed bacteria by using various methods including a filtration aid. Hsu discloses the claimed invention, except that there is no specific teaching that the "filter aid" should be diatomaceous earth. However, a protein chemist in possession of Colpan or Hennan would have recognized that if a filter aid is used, D.E. would have been effective for this purpose.

In response to the foregoing, applicants have argued that the phrase "highly purified" is not used in the reference. Applicants have also argued that the instant claims require that the D.E. meet all of the following criteria:

(i) the D.E. has been leached in acid media (or at least that it be physically and chemically equivalent to D.E. that has been so leached);

(ii) the D.E.has a total SiO_2 content of at least 95%;

(iii) the D.E. has a silica specific volume of at least 3.4.

As it happens, however, none of these limitations is present. The protein chemist or chromatographic specialist (of ordinary skill) is free to interpret the term at issue in any manner which would be reasonable for such a practitioner. The protein chemist or chromatographic specialist (of ordinary skill) would have been motivated to purchase diatomaceous earth from a company that sells it for the purpose of filtration. This is not to say that all grades of D.E. that are sold by reputable companies for the purpose of filtration are necessarily of equal purity. But companies that are in the business of selling D.E. for the purpose of filtration are aware of the need of practitioners to maintain whatever purity of their mixture that they had before the filtration step, i.e., the producers of D.E. filtration aids recognize that if they develop a reputation for selling D.E. which contains readily leachable materials, they will be out of business in short order. Thus, in the interest of maintaining sales, the vendors have a motivation to minimize leachable

materials. As for the "silica specific volume of at least 3.4", the examiner does not argue that a silica specific volume of, e.g., 3.7 is necessarily going to be better for all applications than a specific volume of e.g., 3.4 (or *vice versa*). But the point is moot; the claims do not require this limitation. Further to the foregoing, Hennen discloses (col 10, line 38+) that the D.E. used was Celite that was obtained from the Celite corporation. Surely chemists employed by that company would recognize the need for "highly purified" diatomaceous earth; the executives in charge of the company would recognize the need to adequately serve the marketplace in order to ensure survival. Thus, the Celite referred to qualifies as "highly purified".

The rejection is maintained.

✧

Claims 33-38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Bobbitt (USP 4923967) further in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

The teachings of Hsu, Hennen and Colpan are indicated above. None of these discloses use of sodium thiosulfate or sodium tetrathionate. Bobbitt discloses (col 3, line 27) a process which comprises sulfitolysis; the sulfitolysis may be achieved (col 5, line 24) by use of sodium thiosulfate or sodium tetrathionate.

In response to the foregoing, applicants have implied that the chromatographic specialist or protein chemist of ordinary skill would have been motivated to seek out D.E. that contains readily leachable material. However, there is no reason why this should be so. The chromatographic specialist or protein chemist of ordinary skill would have preferred D.E. that adds no detectable compound(s) to their mixture. Moreover, Hennen discloses (col 10, line 38+) that the D.E. used was Celite that was obtained from the Celite corporation. Given that their livelihoods are staked on the purity and quality of this product, the executives of the Celite corporation would have been motivated to avoid contaminating the materials that are filtered through their product. The rejection is maintained.

✦

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER